

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION)	
_____)	MDL NO. 1203
)	
THIS DOCUMENT RELATES TO:)	
)	
SHEILA BROWN, et al.)	
)	CIVIL ACTION NO. 99-20593
v.)	
)	
AMERICAN HOME PRODUCTS CORPORATION)	2:16 MD 1203
)	

MEMORANDUM AND PRETRIAL ORDER NO.

Bartle, C.J.

August 24, 2007

Christine Haase ("Ms. Haase" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with
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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In January 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, James K. Vincent, M.D., F.A.C.C. Based on an echocardiogram dated December 12, 2001,³ Dr. Vincent attested in Part II of Ms. Haase's Green Form that she suffered from moderate mitral regurgitation and an ejection fraction in the range of 50% to

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serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period, or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. In the Green Form, Dr. Vincent referenced an echocardiogram dated December 11, 2001. The echocardiogram, however, was performed on December 12, 2001.

60%.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$501,985.

In the report of claimant's echocardiogram, Dr. Vincent graded claimant's level of mitral regurgitation as "2 to possibly 3+ in severity." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Vincent also estimated claimant's ejection fraction as 55%. An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id.

§ IV.B.2.c.(2)(b).

In September 2003, the Trust forwarded the claim for review by Eduardo A. Arazoza, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Arazoza concluded that there was a reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Dr. Arazoza, however, concluded that there was no reasonable medical basis for Dr. Vincent's finding that claimant had a reduced ejection fraction. According to Dr. Arazoza, "[t]he EF is normal," which he estimated as being "61% and 65%." Finally, contrary to the

4. Dr. Vincent also attested that Ms. Haase had mild aortic regurgitation. As Ms. Haase's claim does not present any of the conditions necessary to receive Matrix Benefits for damage to her aortic valve, her level of aortic regurgitation is not relevant to this claim. See Settlement Agreement § IV.B.2.c.(2)(a).

attesting physician's finding, Dr. Arazoza found that claimant had pulmonary hypertension secondary to moderate mitral regurgitation.⁵ Under the Settlement Agreement, pulmonary hypertension secondary to moderate or greater mitral regurgitation is defined as peak systolic artery pressure >40 mm Hg measured by cardiac catheterization or >45 mm Hg measured by Doppler Echocardiography, at rest, utilizing standard procedures assuming a right atrial pressure of 10 mm Hg. See id.

Based on Dr. Arazoza's diagnosis of a normal ejection fraction, the Trust issued a post-audit determination denying Ms. Haase's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant submitted a

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust concedes that there was a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation, the only issue is whether claimant has a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim. Given our ultimate resolution of claimant's ejection fraction, we need not address the auditing cardiologist's finding that claimant had pulmonary hypertension, which also is one of the complicating factors needed to qualify for a Level II claim.

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms.

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supplemental report from Dr. Vincent, dated May 5, 2004, and her clinical records.⁷ In the report, Dr. Vincent confirmed his finding of a reduced ejection fraction. Claimant also argued that her ejection fraction was "irrelevant" to her level of mitral regurgitation, as she has mild aortic regurgitation, moderately severe mitral regurgitation, and "evidence of pulmonary valve disease."

The Trust then issued a final post-audit determination, again denying Ms. Haase's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2807 (Mar. 26, 2003); Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Haase's claim should be paid. On May 20, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5239 (May 20, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Despite the opportunity in the show cause process to brief the disputed issues, claimant did not file a response to

6(...continued)
Haase's claim.

7. Claimant also submitted echocardiogram reports dated September 25, 2002 and September 18, 2003. She, however, did not submit copies of the echocardiogram tapes underlying these reports. The Green Form was based on the echocardiogram dated December 12, 2001.

the Trust's statement of the case. See Audit Rule 25. Instead, claimant chose to rely entirely on the arguments raised during the contest phase of the audit process. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁸ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. Id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had a reduced ejection fraction. See id. Rule 24. Ultimately, if we determine that there was no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there was a reasonable medical

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement.

See id. Rule 38(b).

Dr. Vigilante reviewed claimant's echocardiogram and concluded that there was a reasonable medical basis for the attesting physician's finding of a reduced ejection fraction.⁹ Specifically, Dr. Vigilante stated that:

Measurements of left ventricular end systole and left ventricular end diastole were made and calculations of the ejection fraction were performed via Simpson's Rule. The left ventricular ejection fraction was between 55% and 61% in these representative cardiac cycles

[T]here is a reasonable medical basis for the Attesting Physician's answer to Green Form Question F.8. That is, the echocardiogram of December 11, 2001 demonstrated an ejection fraction of 55% to 61%. Therefore, there was a reasonable medical basis for the Attesting Physician's answer that the Claimant's ejection fraction was in the range of 50%-60%.

After reviewing the entire Show Cause Record before us, we find that claimant has established a reasonable medical basis for her claim. Claimant's attesting physician reviewed claimant's echocardiogram and found that claimant had a reduced ejection fraction, which he estimated as 55%. Although the Trust contested the attesting physician's conclusion, Dr. Vigilante

9. Dr. Vigilante, however, determined that claimant did not have pulmonary hypertension.

confirmed the attesting physician's finding.¹⁰ Specifically, Dr. Vigilante concluded that "there was a reasonable medical basis for the Attesting Physician's answer that the Claimant's ejection fraction was in the range of 50%-60%."

As stated above, an ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See Settlement Agreement § IV.B.2.c.(2)(b). Here, Dr. Vigilante determined that claimant's ejection fraction was between 55% and 61%. Under these circumstances, claimant has met her burden in establishing a reasonable medical basis for her claim.¹¹

For the foregoing reasons, we conclude that claimant has met her burden in proving that there is a reasonable medical basis for her claim and is consequently entitled to Level II Matrix Benefits. Therefore, we will reverse the Trust's denial of the claim submitted by Ms. Haase for Matrix Benefits.

10. Despite an opportunity to do so, the Trust did not submit any response to the Technical Advisor Report. See Audit Rule 34.

11. Accordingly, we need not address claimant's remaining arguments.

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AND NOW, on this 24th day of August, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the final post-audit determination of the AHP Settlement Trust is REVERSED and that claimant Christine Haase is entitled to Level II Matrix Benefits. The Trust shall pay such benefits in accordance with the Settlement Agreement and Pretrial Order No. 2805 and shall reimburse claimant for any Technical Advisor costs incurred in the Show Cause process.

BY THE COURT:

/s/ Harvey Bartle III

C.J.